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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,165	06/01/2001	Peter C. Brooks	13761-0754	8769

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EXAMINER	
YAEN, CHRISTOPHER H	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,165	BROOKS ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *6-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1/29/2002* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

RE: Brooke *et al*
Priority Date: 01 June 2001

Election/Restrictions

1. Applicant's election without traverse of group I (claims 1-5) in Paper No. 10312003 is acknowledged.

2. Claims 1-35 are pending, claims 6-35 are withdrawn from further consideration as being drawn to a non-elected invention.

3. Claims 1-5 are examined on the merits.

Information Disclosure Statement

4. The Information Disclosure Statement filed 1/29/2002 (paper no. 1292003) is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections - 35 USC § 112, 2nd paragraph

5. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. With regard to claim 1 and dependent claims thereof in the recitation of the term "substantially equivalent", it is vague and indefinite because it is not clear either from the specification nor the claims as to the degree of equivalence. One of skill in the art

cannot reasonably determine the full scope of this term, and therefore the metes and bounds are unclear.

Claim Rejections - 35 USC § 112, 1st paragraph

7. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case has only set forth a peptide sequence that consists of SEQ ID No: 1 and 2 useful for the inhibition of angiogenesis, angiogenesis related disorders and diseases, and the treatment of metastasis and therefore the written description in this case is not commensurate in scope to claims that read on peptides which are "substantially equivalent" to SEQ ID No: 1 or 2 which is useful for the inhibition of any disease.

The claims recite a peptide that is "substantially equivalent" to that of SEQ ID No: 1 or 2 which is useful for the treatment of diseases in general. The specification teaches that SEQ ID No: 1 and SEQ ID No: 2 are derived from MMP-2 and that such peptide fragments are useful for the inhibition of angiogenesis and in the inhibition of metastasis in an animal model. However, it appears that the specification has not taught equivalents or variants of SEQ ID No: 1 or 2 (i.e. specific modification such as additions, deletions, or substitutions), and as such, the skilled artisan would not be able to determine what sequences are intended within the scope the claims. In order to

comply with the requirements of written description, essential structural features that provides the recited function of inhibiting angiogenesis is required. Furthermore, it is claimed that the peptides are to be used in the treatment of any disease. The specification has only provided a small subset of diseases, namely those that involve angiogenesis, and is therefore not entitle to the broad scope of any disease. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Applicant does not appear to have reduced to practice any "equivalents" that are substantially identical to that of SEQ ID No: 1 or 2. Neither has Applicant provided a sufficient written description of any structure that may be correlated with the desired angiogeneic function. The genus of compounds encompassed by this term is extensive and the artisan would not be able to recognize that Applicant was in possession of the invention as now claimed. In addition, the specification has only taught diseases that

are involved in angiogenesis and has not taught a full range of diseases, so as to be entitled to the broad genus of any disease claimed.

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 112, 1st paragraph

8. Claims 4-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a peptide of SEQ ID No: 1 or 2 for the treatment of angiogeneic related cancer and diseases asscoaited with angiogenesis, does not reasonably provide enablement for a peptide of SEQ ID No: 1 or 2 for the treatment of diseases in general nor for the broad class of neurological disease. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification teaches a peptide of SEQ ID No: 1 and 2 wherein the peptide is involved in the inhibition of diseases associated with angiogenesis, including cancer. However, the specification has not taught how the peptides are to be used in the treatment of the any disease, wherein the disease is not associated with angiogenesis.

The art teaches that the some disease are often difficult to treat and often provide unpredictable outcomes. One such disease is immune thrombocytopenic purpura (ITP). It is taught by Stasi *et al* (Mayo Clin Proc. 2004 Apr;79(4):504-22) that this autoimmune disease is "heterogeneous with regard to severity and clinical course and is unpredictable in its response to therapy" (see abstract). Because the specification has only taught the use of the peptide of SEQ ID No: 1 or 2 in the treatment of a specific type of disease, namely diseases associated with angiogeneic events (i.e. psoriasis, macular degeneration, and cancer), one of skill in the art cannot reasonable extrapolate this information in the treatment of any and all types of diseases. There must be a reasonable correlation between what is claimed and what is taught in the specification so that one of skill in the art can make a reasonable link or nexus between the teachings of the specification and the application of the claimed invention. Because the specification has not taught the treatment of the diseases in general, and has only provide evidence or guidance for the treatment of disease associated with angiogenesis, the skilled artisan cannot apply the peptides as claimed for the treatment of ITP, for example, because the specification has not shown that a disease which is

regarded as an unpredictable diseases can be treated with the instantly claimed peptide of SEQ ID No: 1 or 2.

Therefore, given the broad range of diseases encompassed by the claims, which includes ITP and absent sufficient teachings in the specification to overcome the teachings of unpredictability found in the art, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldberg GI (WO 98/12309). Claims are drawn to a peptide comprising a sequence substantially equivalent to a sequence selected from the group consisting of SEQ ID No: 1 or 2 (claim 1), wherein the peptide inhibits angiogenesis (claim 2), metastasis (claim 3), and a disease (claim 4), wherein the disease is psoriasis, macular degeneration, neurological disease, or restenosis (claim 5).

Goldberg GI discloses a peptide that is identical to that of SEQ ID No: 1 (see page 38) and further discloses a sequence that is "substantially equivalent" to SEQ ID No: 2, wherein the difference between the peptide disclosed by Goldberg GI and of

SEQ ID No: 2 is that there are no cysteines located at either the C or N terminal ends (see page 38).

Although Goldberg GI does not specifically teach that the peptide sequences are involved in inhibiting angiogenesis, metastasis, or a disease, he does teach that these inhibitors can be used for the treatment of disease that involve tissue repair and damage, such as rheumatoid arthritis, and restenosis. Thus, while Goldberg GI does not characterize the peptide that is identical to SEQ ID No: 1 and substantially equivalent to SEQ ID No: 2 as being anti-angiogenic, the claimed functional limitation would be an inherent property of the peptide claimed. Thus, it does not appear that the claim language or limitation results in a materially different peptide that has distinct functional properties when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

11. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Brooks P *et al* (WO 97/45137). See above for claim limitations. Brooks P *et al* disclose a peptide that is identical to that of SEQ ID No: 1 (see page 151) and a peptide that is "substantially equivalent" to SEQ ID No: 2, wherein the difference between the peptide disclosed by Brooks P *et al* and of SEQ ID No: 2 is that there are no cysteines located at either the C or N terminal ends (see page 151). Further, Brooks P *et al* disclose that the peptide is capable of inhibiting angiogenesis, metastasis, and other diseases, such as macular degeneration.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
December 18, 2003

GARY NICKOL
PRIMARY EXAMINER